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PLEASE STAMP TO ACKNOWLEDGE RECEIPT OF THE FOLLOWING:

In Re Application of: Jacques MALLET et al.

Serial No.: 09/578,453 Group Art Unit: 1632

Filed: May 26, 2000 Examiner: P. Brunovskis

For: PHARMACEUTICAL COMPOSITIONS AND UTILIZATION THEREOF PARTICULARLY FOR THE TREATMENT OF NEURODEGENERATIVE DISORDERS

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1. Response to Restriction Requirement

Dated: October 18, 2001

Docket No.: 03804.0114-02000 (Due Date: November 2, 2001

WLS/cob - **MailDrop 216**

217176-1

PATENT
Customer No. 22,852
Attorney Docket No. 03804.0114-02000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Jacques MALLET *et al.*

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For: PHARMACEUTICAL COMPOSITIONS AND UTILIZATION THEREOF PARTICULARLY FOR THE TREATMENT OF NEURODEGENERATIVE DISORDERS

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Examiner: P. Brunovskis

Commissioner for Patents and Trademarks
Washington, DC 20231

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

In a restriction requirement mailed October 2, 2001, the Examiner required restriction under 35 U.S.C. § 121 between the following groups:

Group I: Claims 16-22, 25, and 26, allegedly drawn to a recombinant virus comprising a nucleic acid encoding a mutated form of p53 and its use in a method for inhibiting toxicity in cultured cells;

Group II: Claims 16-20, 22, 25, and 26, allegedly drawn to a recombinant virus comprising a p53 binding site and its use in a method for inhibiting toxicity in cultured cells;

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Group III: Claims 16-22 and 23-26, allegedly drawn to a recombinant virus comprising a nucleic acid encoding an antisense RNA that inhibits the expression of p53 and its use in a method for inhibiting toxicity in cultured cells; and

Group IV: Claims 27-31, allegedly drawn to a method for identifying compounds that inhibit p53 activity.

Applicants provisionally elect to prosecute Group I, claims 16-22, 25, and 26, allegedly drawn to a recombinant virus comprising a nucleic acid encoding a mutated form of p53 and its use in a method for inhibiting toxicity in cultured cells with traverse.

Applicants contend that the requirement for restriction between the claims in Groups I, II, and III is improper. All three groups comprise claims 16-20, 22, 25, and 26. Applicants respectfully submit that they have a statutory right under 35 U.S.C. § 112, second paragraph, to claim the subject matter they regard as their invention as they choose. Issuing a restriction requirement within a claim with the idea that Applicants would have to carve up that claim and pursue the nonelected subject matter in a separate application violates this right under section 112. Indeed, the C.C.P.A. has characterized such action as tantamount to a refusal to examine. *See In re Weber*, 198 U.S.P.Q. 328 (C.C.P.A. 1978); *In re Haas*, 198 U.S.P.Q. 334 (C.C.P.A. 1978).

In *Weber*, the court warned against the consequences of requiring an applicant to divide up the subject matter presented in a single claim, stating:

> As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits.

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> The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

Weber at 331.

35 U.S.C. § 121 gives the Office authority to promulgate rules designed to restrict an application to one of several claimed inventions when those inventions are found to be independent and distinct. 35 U.S.C. § 121, however, does not give the Office authority to reject a particular claim on that basis. *Weber* at 332.

In addition, the Office has provided no reasons or examples as required by M.P.E.P. §803 to support its conclusion that the recombinant viruses recited by the claims in Groups I, II, and III are different inventions. The Office simply states:

> Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are related to different methods, restriction is deemed to be proper between the methods of I-IV since they constitute patentably distinct inventions comprising different methodologies, different recombinant viruses encoding or comprising different active agents operating by different mechanisms by processes involving different technical considerations (e.g. mutant proteins, binding sites antisense RNAs) or reagents (e.g. glutamate), method steps (measurement of excitotoxicity), and technical considerations and/or endpoints as a whole requiring separate non-coextensive searches."

(Office Action mailed October 2, 2001, pages 3-4.)

However, the Office acknowledges that the allegedly distinct inventions of Groups I, II, and III all are classified in class 424, subclass 93.2. (*Id.*, page 2.) The Office has offered no basis for concluding that searching the subject matter of Groups I, II, and III would present an undue burden. In fact, the Office has provided no substantive reason to violate Applicants' statutory right under 35 U.S.C. § 112, second paragraph, to claim the subject matter they regard as their invention as they choose.

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Thus, in order to avoid unnecessary delay and expense to Applicants and duplicative examination by the Patent Office, the restriction among Groups I, II, and III should be withdrawn.

For the reasons above, Applicants request the reconsideration and withdrawal of the restriction requirement among Groups I, II, and III.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: October 18, 2001

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